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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

POTHIER, DENISE M

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/787,171

Applicant(s)

SMITS, JAN F.A.

Examiner

Denise M Pothier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: it appears that the specification is single-spaced. Section 1.52(b)(2)(i) of 37 C.F.R. requires that the specification be 1 ½ or double-spaced.

Appropriate correction is required.

### *Claim Objections*

2. Claims 6-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6-10 have not been further treated on the merits.
3. Claims 1-5 are objected to because of the following informalities: the inclusion of the phrase, "characterized in that" in claims 1-5, is grammatically awkward. Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The non-statutory subject matter of claim 1 is the positive recitation to body parts. The recitation, "on point on the medial side of first

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phalanx of the big toe," makes the medial side of the toe an integral component of the claim. To overcome this rejection, Applicant should recite -- sized and configured to be located on the medial side of the toe --. In addition, please review the rest of claim 1 and the other claims for other positive recitations to body parts and correct accordingly.

6. The remaining claims are necessarily rejected because they depend from a rejected claim.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The recitation, "three point lever means designed to be located distally of the metatarsal joint" in claim 1, line 3 is indefinite. Webster's II New Riverside Dictionary defines "distal" as "located far from the origin or line of attachment, as a bone." From Figure 1 of Applicant's specification, one point (B) is not located distally of the metatarsal joint.

10. The claim 1 remains indefinite since it is not clear whether Applicant intends to recite parts of the body as integral components of the claim.

11. The recitation, "which is slidable and may be fixed with glue" in claim 5, is indefinite since it is not clear whether the sleeve is fixed or not.

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12. Claim 5 recites the limitation "the adjustable arm" in line 1. There is insufficient antecedent basis for this limitation in the claim.

13. The remaining claims are rejected because they depend from a rejected claim.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-5, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Day (2,416,823). Day discloses in Figures 1-4 a hallux valgus brace (col. 1, l. 5-7) comprising a three point lever means designed to be located distally of the metatarsal joint (see Figs. 1-4), one point of the three point lever means being sized and configured to be located on the medial side of the first phalanx of the big toe (see 26 in fig. 8), one point being sized and configured to be located on the lateral side of the distal end of the big toe (see 48) and one point being sized and configured to be located on the ball of the foot (see 24 in Fig. 8).

As for claim 2, see Figures 1 and 3, column 1, lines 44-45 and column 2, lines 2, line 16 of Day regarding the distal and proximal pads. With respect to the lever arm, see elements 24 and 44 in Figure 1 of Day adapted to press on the ball of the foot.

As for claim 3, see Figures 1 and 3 of Day showing the distal pad (48) adapted to press on the distal end of the first phalanx of the big toe.

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As for claim 4, Day discloses the distal pad 48 is disposed on an arm (46). Also, Day discloses in column 2, line 55 through column 3, line 8 that the arm 46 is elastic and thus adjustable.

As for claim 5 as best understood, Day discloses the adjustable arm (46) is secured to a sleeve (pocket 34 in Figures 5 and 6), which is slidable relative to the padding 26 secure to the pocket and relative to the user's foot.

16. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcus (3,049,120). Marcus discloses in Figures 6-9 a hallux valgus brace (col. 1, l. 8-20) comprising a three point lever means (includes 11,49,67,68) designed to be located distally of the metatarsal joint (seen best in Fig. 7), one point of the three point lever means being sized and configured on the medial side of the first phalanx of the big toe (see around 11 in Fig. 6), one point sized and configured to be on the lateral side of the distal toe (see 49 in Fig. 5) and one point (see element 67 in Figs. 7 and 9) being sized and configured to be located on the ball of the foot, as best understood.

As for claim 2, proximal pad of Marcus includes element 11, the distal pad includes element 49 and the lever arm includes element 67 configured to press on the ball of the foot. Note the specification describes the pads as being made of steel (p. 2, l. 30) and does not describe any cushioning. As such, a broad interpretation of the word, "pad," is being taken for purposes of examination.


As for claim 3, the distal pad of Marcus is adapted to or capable of pressing on the distal end of the first phalanx of the first toe (see Figs. 7 and 10).

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17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jungmann (4,637,381 and 2,099,401) and Kashara (5,437,616) disclose the state of the art of hallux valgus devices. Goldmerstein (2,335,665), Baltor (2,471,997), Kiwad (2,531,85), Day (2,190,016), Scholl (1,055,810) and Stern (1,784,032) disclose the state of the art of toe straightening and protecting devices. Funatogawa (5,076,263) discloses a toe stretcher. Takeuchi discloses a toe appliance with various toe-engaging mechanisms. Belkin (6,110,136) discloses a splint that can be placed over toe.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise M. Pothier whose telephone number is 703.308.0993. The examiner can normally be reached on Monday-Thursday and alternate Fridays. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

**Any inquiry of a general nature or relating to the status of this application** or proceeding should be **directed to the receptionist** of Technology Center 3700, whose telephone number is (703) 308-1148.

  
Denise Pothier  
Primary Examiner  
November 5, 2002